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**Final Report
of the
MAINE DRUG RETURN IMPLEMENTATION
GROUP**

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Executive Summary

Public Law 2003, Chapter 679 created the Unused Pharmaceutical Disposal Program administered by the Maine Drug Enforcement Agency and established the Maine Drug Return Implementation Group. The implementation group is charged with working on implementation issues for the Unused Pharmaceutical Disposal Program, specifically addressing postal regulations, methods and requirements for packaging for mailing, minimizing drug diversion and theft, public education and encouraging the development of turn-in programs. The public law is included in Appendix A.

History

The implementation group was formed during the fall of 2004, with appointment of 2 members of the House, one member of the Senate, representatives of Maine police chiefs, pharmacies, pharmaceutical manufacturers, an association of medical professionals, the Office of the Attorney General, the Department of Health and Human Services, the Department of Environmental Protection and the Maine Drug Enforcement Agency. The membership of the implementation group is included as Appendix B.

The implementation group held 4 public meetings to review information on environmental and pharmaceutical issues, to receive briefings and to reach consensus on recommendations. The meetings were held in Augusta on October 15, November 12 and December 20, 2004, and January 28, 2005.

Recommendations

- The implementation group recommends the encouragement of local turn-in events for people to drop off unneeded pharmaceuticals for disposal. These programs rely on the voluntary action of individuals, local municipalities, community service organizations and law enforcement agencies for success. The implementation group suggests that the Legislature consider product stewardship, in which the pharmaceutical manufacturers would fund or provide funding for all aspects of local turn-in events.
- The implementation group recommends amendments to the Maine Unused Pharmaceutical Disposal Program, Public Law 2003, Chapter 679, to allow public funding that is not from the General Fund and delay the start date to July 1, 2006. See draft legislation in Appendix E. Once again, product stewardship could be considered to provide funding for the mail-in program.
- The implementation group supports consideration of a drug redistribution program that would accept unneeded, unopened prescription drugs for redistribution to qualified persons who hold prescriptions for those drugs. See Appendix F.
- The implementation group recommends that the Maine Drug Enforcement Agency send a letter to the United States Drug Enforcement Administration supporting amendment to federal regulations to provide a safe and effective method of disposal for controlled substances for individual citizens and law enforcement.

I. INTRODUCTION

Public Law 2003, Chapter 679 created the Unused Pharmaceutical Disposal Program administered by the Maine Drug Enforcement Agency and established the Maine Drug Return Implementation Group. The implementation group is charged with working on implementation issues for the Unused Pharmaceutical Disposal Program, specifically addressing postal regulations, methods and requirements for packaging for mailing, minimizing drug diversion and theft, public education and encouraging the development of turn-in programs. A copy of Public Law 2003, Chapter 679, is attached as Appendix A.

The implementation group was formed during the fall of 2004, with appointment of 2 members of the House, one member of the Senate, and representatives of a local police department, pharmacies, pharmaceutical manufacturers, an association of medical professionals, the Office of the Attorney General, the Department of Health and Human Services, the Department of Environmental Protection and the Maine Drug Enforcement Agency. In addition, the implementation group maintained contact with and invited the participation of representatives of the Office of the United States Attorney for Maine, the United States Drug Enforcement Administration in the United States Department of Justice and the United States Postal Service. A copy of the membership of the implementation group is included as Appendix B.

The implementation group held 4 public meetings to review information on environmental and pharmaceutical issues, receive briefings on state pharmaceutical programs and state and federal law and reach consensus on recommendations. The meetings were held in Augusta on October 15, November 12 and December 20, 2004, and January 28, 2005.

II. BACKGROUND INFORMATION

A. Defining the problem

Unneeded prescription drugs can be a problem. Kept at home, they stack up in the medicine cabinet, age beyond their expiration dates and tempt unsafe use and intentional abuse. Newspaper accounts offer frightening accounts of home invasions with the intent of obtaining prescription narcotics such as OxyContin. Pharmacies are reluctant to take back unneeded drugs or are prohibited by law from doing so. Disposing of unneeded drugs by flushing them down the toilet or discarding them in the trashcan, so that they end up in a landfill, carries risks to the environment. What is a person to do?

B. Environmental issues

Evidence of pharmaceuticals and personal care products (PPCPs) is showing up in tests conducted on various bodies of water around the globe. Scientific testing points to the need for more research, increased public awareness and better stewardship of the world's surface and groundwaters. A leading researcher on PPCPs, Christian Daughton, of the US Environmental Agency, National Exposure Research Laboratory, has called for increased collaboration between

the environmental and medical fields to determine the causes, extent, risks and solutions to the issue of drugs as pollutants. (*Environmental Stewardship and Drugs as Pollutants*, The Lancet, October 5, 2002, by Christian G. Daughton)

Following are some examples of studies on pharmaceuticals and personal care products and their findings:

- Traces of pharmaceuticals and personal care products have been found by the US Geological Survey downstream of wastewater treatment plants and livestock farms in 139 rivers in 30 states. (*Algae Laid Low by Soap and Toothpaste*, Science Update, November 14, 2004 by Hannah Hoag, citing research by Dana Kolpin in 1999 and 2000) Researchers tested for 95 different organic compounds found in pharmaceuticals and household chemicals. At least one of the target organic compounds showed up in 80% of the waterways, with an average of 7 organic compounds per stream and a maximum of 38 organic compounds in one stream.
- Chemicals that find their ways into streams, by way of sewage, and that are not effectively destroyed by sewage treatment plants include antibiotics, antidepressants, anti-cancer drugs, tranquilizers, blood lipid regulators and other well-known drugs such as Viagra. (*Pharmaceuticals and Personal Care Products in the Environment: Agents of Subtle Change?* Environmental Health Perspectives, December 1999 by Christian Daughton and Thomas Ternes)
- One NuvaRing women's controlled release estrogen dispenser contains after use 2.4 milligrams of estrogen, enough to interfere with the reproduction systems of fish. (*Contraceptive Ring Could Pose Risks After Its Disposal*, Science News, January 25, 2004, by Janet Raloff)

The scientific community recognizes that further research is warranted on the environmental impact of pharmaceuticals and personal care products that reach the environment through excretion from the body, washing dermally applied medications or disposal through flushing or landfilling. Some deposition is inevitable as wastewater cannot treat for most pharmaceuticals and personal care products, but improper flushing is avoidable with consumer education and the development of sound disposal options.

C. Federal and state requirements

Hazardous waste

The Federal Resource Conservation and Recovery Act (RCRA) classifies household pharmaceuticals as household hazardous waste and exempts them from federal regulations governing the disposal of hazardous waste. Having adopted the provisions of RCRA, Maine has chosen to regulate household pharmaceuticals as solid waste, making disposal of unneeded drugs by a household member in a landfill or sewer system legal. When prescription drugs are separated from household waste and accumulated from more than one individual, those accumulated drugs are considered hazardous waste under state and federal laws and must be disposed of in compliance with those requirements.

A drug that is a controlled substance, categorized on a federal list as Schedule II through V, is viewed differently from pharmaceuticals that are not controlled substances. Once a controlled substance is in the hands of the prescription holder, a law enforcement agent in the course of conduct of official duties is authorized to accept that drug. The officer must dispose of accumulated controlled substances as hazardous waste through a witnessed burn at a licensed waste incinerator. Federal law prohibits all others, including reverse distributors, from accepting controlled substances from individuals and law enforcement officers, thus increasing the difficulty and cost of law enforcement in effecting disposal.

Some prescription and nonprescription drugs are considered hazardous waste because of their chemical make-up or characteristics. These drugs also must be disposed of as hazardous waste, at a licensed hazardous waste incinerator facility. If they are not controlled substances disposal does not have to be by a witnessed burn.

Mailing and shipping requirements

A program for mailing in unneeded prescription drugs must comply with federal requirements for mailing, following the US Postal Service Domestic Mail Manual and the rules adopted under that manual,. The program must also comply with any requirements from the Controlled Substances Act, the U.S. Environmental Protection Agency and the U.S. Drug Enforcement Administration. As prescription drugs already regularly travel via the mail in this country to consumers, the technology of appropriate packaging exists and is reasonably priced.

Sending accumulated unneeded prescription drugs out of state for disposal as hazardous waste requires the services of a licensed transporter of hazardous waste. The implementation group noted that hiring personnel to identify and separate controlled substances from other drugs could be very expensive but would lower disposal costs for the drugs that are not controlled substances. Not separating the drugs would save on substantial personnel costs and increase disposal costs as all of the drugs would have to be disposed of as if they were controlled substances.

D. Current approaches

Lacking clear direction on methods for disposing of unneeded prescription drugs, Maine residents choose a variety of approaches. They store them up at home, seek the cooperation of their dispensing pharmacy to take them back and dispose of them, flush them into the sewer and send them to the landfill or incinerator plant. The Penobscot County AARP Triad has just begun small scale turn-in events and a larger 1-day event held in South Portland at a pharmacy resulted in the collection of 55,000 pills, enough to fill a 55 gallon container. Public Law 2003, Chapter 679 establishes a mail-in program contingent on acquiring outside funding which is scheduled to begin July 1, 2005 if funding is available.

The implementation group reviewed the volume of drugs being prescribed, the practices of Maine's nursing facilities and hospitals and the requirements of the MaineCare program. Data presented to the group provided a snapshot of the type and amount of drugs being prescribed in the state. The implementation group appreciates the cooperation of the Maine Health Care

Association, the Maine Hospital Association, the MaineCare program within the Department of Health and Human Services, Anthem Blue Cross Blue Shield, the Maine State Employees Health Insurance Program, the University of Maine Systems health plan and the Maine Education Association Benefits Trust.

From the information provided, the implementation group considered the following items to be particularly useful when looking at the big picture of prescription drugs and their disposal:

- Maine's nursing facilities are aware of the problem of unneeded prescription drugs, of the need for safe disposal and the potential benefits of returning unneeded drugs. Controlled substances and medicines that come in bulk and formulations such as ointments and cortisone must be regularly and methodically destroyed. Unit doses that are unopened are returned to the pharmacy for credit and repackaging whenever possible. Handling of medications is done only by trained staff, with paperwork requirements and storage and dispensing procedures that would not be practical in a household setting.
- Maine's hospital pharmacies handle a broad array of prescription drugs. They utilize reverse distributors, which are companies that accept unused drugs, return whatever is possible to the manufacturers and dispose of expired and out of date drugs, drugs the manufacturers would not accept back and drugs on the federal RCRA list. Drugs that are not hazardous waste under Maine DEP rule may be managed as medical waste and incinerated. RCRA hazardous waste drugs are disposed of as hazardous waste and are shipped to disposal sites out of state. Unmedicated intravenous fluids and controlled substances are disposed of into the sewer system.
- The MaineCare program reimburses pharmacies and hospitals for prescription drugs for members enrolled in the MaineCare program. In order to avoid excess dispensing, MaineCare controls the length of time for which drugs may be dispensed, according to the nature of the drug. The program requires nursing and other health care facilities to identify unneeded drugs on a monthly basis, requires that drugs in unit dose packages be returned for credit and requires the destruction of unneeded medications not returned for credit.
- In order to learn the extent of prescription drug use in Maine, the implementation group reviewed the quantities of prescription drugs reimbursed each month by 3 large health coverage programs. The Maine State Employees Health Insurance Program reimburses pharmacies for an average of 136,427 prescriptions each month, of which 2193 are for narcotics. The Maine Education Association Benefits Trust reimburses pharmacies for an average of 205,474 prescriptions per month, of which 2629 are for narcotics. The University of Maine Systems health plan reimburses pharmacies for an average of 40,500 prescriptions per month, of which 533 are for narcotics.

III. RECOMMENDATIONS

A. Voluntary turn-in events

The implementation group reviewed voluntary turn-in events for unneeded prescription drugs and recommends encouraging turn-in events on the local level. The implementation group anticipates an increasing number of these events and greater amounts of collected unneeded drugs. The implementation group recommends that the Legislature consider product stewardship for voluntary turn-in events in order to provide continuing responsibility from pharmaceutical manufacturers for their products, including funding for education, outreach, collection, disposal and reporting.

Coordination

The implementation group recommends that the Maine Department of Environmental Protection, the Maine Drug Enforcement Agency, the Department of Health and Human Services and the Department of the Attorney General work together with manufacturers to enable more turn-in events to be held successfully. Coordination is needed to ensure that turn-in events are safe and convenient for individual citizens who participate, provide safeguards for the collection and identification of turned-in drugs and comply with state and federal law and rule regarding the handling of controlled substances and hazardous waste. The implementation group suggests that a statistically valid sampling of collected unneeded drugs be done and recorded to provide information about drug prescribing and waste.

Educational materials and outreach

The implementation group suggests that the Office of the Attorney General, the Departments of Environmental Protection and Health and Human Service, the Maine Medical Association and the Maine Hospital Association work together to prepare informational materials for interested parties, participating municipalities, law enforcement, medical personnel and community service organizations. Good information on how to successfully hold a voluntary turn-in event will increase the number of events, public participation and success.

Funding

Funding for collection, transportation, storage and disposal would enable a greater number of turn-in events to be held successfully. Funds may be needed for law enforcement, statistical sampling, reporting and disposal. The implementation group suggests that individuals and entities interested in voluntary turn-in events pursue funding for their local events and that the Legislature consider product stewardship to provide funding.

Starting date

A starting date for voluntary turn-in events is not required because of their voluntary nature. If product stewardship were applied to voluntary turn-in events, a start date would be needed for manufacturer responsibility to begin.

B. Mail-in program

Public Law 2003, Chapter 679, which created the Unused Pharmaceutical Disposal Program, recognized that the enabling legislation was incomplete and established the implementation group to provide guidance to the Legislature. Specifically the legislation mentions the need for recommendations regarding postal regulations, methods and requirements for mailing packaging, minimizing drug diversion and theft and public education. The implementation group reached consensus on recommendations to move the disposal program forward. The implementation group recommends that the Legislature consider adding a product stewardship model to the mail-in program.

Packaging for mailing

The implementation group suggests that pharmaceutical manufacturers or the State or both provide the mailing packaging for the mail-in program that meets the requirements of the United States Postal Service and the Maine Drug Enforcement Agency. The implementation group recommends that the mailing packaging be made available at pharmacies, hospitals, physicians' offices and health clinics.

Mail receipt, storage and disposal

The implementation group recommends that the Maine Drug Enforcement Agency determine whether drugs would be mailed directly to MDEA or to a consolidator under contract with MDEA. MDEA rulemaking is necessary to establish the protocols for mailers and mailing, statistical sampling and reporting and disposal of drugs. Transportation to a disposal site, which is required to be done by a licensed handler of hazardous waste, would be accomplished by the consolidator. Hazardous waste disposal sites would accept the shipments of unneeded drugs shipped from Maine and would dispose of them by incineration.

Educational materials and outreach

The implementation group suggests that educational materials for pharmaceutical manufacturers, pharmacies, hospitals, physicians' offices, health clinics, law enforcement and individual citizens be provided by the Office of the Attorney General, the Departments of Environmental Protection and Health and Human Service, the Maine Medical Association, the Maine Hospital Association and the drug manufacturers, all within the limits of their existing resources.

Funding

Public Law 2003, Chapter 679 requires non-public funding in order to begin the mail-in program. Funding will be required for the prepaid mailers, distribution, postage, storage and disposal and public education materials. The implementation group recommends that Public Law 2003, Chapter 679 be amended in 22 MRSA section 2700, subsection 5, to allow receipt of non-General Fund public funding, including federal funds. Suggested legislation is included as Appendix E.

Starting date

The implementation group recommends that the starting date for the Unused Pharmaceutical Disposal Program be changed to allow for additional preparation time for the adoption of rules and the acquisition of funding. The implementation group recommends that Public Law 2003, Chapter 679, section 4 should be amended to provide for an effective date of July 1, 2006. Suggested legislation is included as Appendix E.

C. Product stewardship

Product stewardship is a concept that recognizes the responsibility of the manufacturer of a product from the manufacturing process through final disposal in an environmentally sound manner. The implementation group recommends that the Legislature consider a product stewardship model for voluntary turn-in programs and the mail-in program for prescription drugs, recognizing the cooperative efforts of individual citizens, prescription drug manufacturers and State government to provide safe collection and disposal for those drugs. If product stewardship were to be adopted by the Legislature, the implementation group recommends a starting date of July 1, 2007.

D. General recommendations

- The implementation group recommends that the Maine Legislature consider legislation to establish a redistribution program for unneeded pharmaceuticals. Under this program Maine residents of low and medium income who hold a valid prescription would be eligible to obtain for a very low fee prescription drugs that had been donated to the program from health facilities, drug manufacturers, drug wholesale and terminal distributors and hospitals. The drugs would all be unopened and packaged in tamper-evident unit dose packages or they would be unopened injectable, aerosol or topical medications. The program would not distribute controlled substances, drugs that had been tampered with or drugs within 6 months of their expiration date. See Appendix F for suggested legislation.
- The implementation group recommends that a letter be sent by the Maine Drug Enforcement Agency to the United States Drug Enforcement Administration supporting amendment to federal regulations to provide individual citizens and law enforcement safe and effective methods of disposal for controlled substances.

APPENDIX A

Public Law 2003, Chapter 679

An Act to Encourage the Proper Disposal of Unneeded Pharmaceuticals

APPENDIX B

Membership list, Maine Drug Return Implementation Group

APPENDIX C

Chart of Options for Drug Return Programs

APPENDIX D

Origins and Fate of PPCPs in the Environment

By Christian G. Daughton

<http://epa.gov/nerlesd1/chemistry/pharma/images/drawing.pdf>

APPENDIX E

An Act Regarding the Unneeded Pharmaceutical Disposal Program

APPENDIX F

An Act to Establish the Unneeded Prescription Drug Redistribution Program